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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,070	11/24/2000	Brian S. Kelleher	18608002910	3576

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EXAMINER

DOERRLER, WILLIAM CHARLES

ART UNIT PAPER NUMBER

3744

DATE MAILED: 08/24/2004

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 09/722,070
Filing Date: November 24, 2000
Appellant(s): KELLEHER ET AL.

MAILED
AUG 24 2004
GROUP 3700

Jonathan Spangler
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6-28-2004.

(1) *Real Party in Interest*

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A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The appellant's statement that the claims stand or fall together is correct.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

5,775,331	RAYMOND et al	7-1998
6,027,456	FELER et al	2-2000
5,284,153	RAYMOND et al	2-1994

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5,284,154	RAYMOND et al	2-1994
5,830,151	HADZIC et al	11-1998

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 15,16,22-26,30,31 and 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raymond et al '331 in view of Feler et al.

Raymond et al '331 discloses applicants' basic inventive concept, a method for determining the location of a nerve by electrically signaling the nerve and detecting the response and determining when the signal is below a threshold signifying close proximity to the nerve (see abstract) and using a visual or audible alarm to signal the proximity to the nerve, substantially as claimed with the exception of using the process on a spinal nerve. While this is seen as a matter of design choice since all the nerves in a body function on the same principle, Feler et al nevertheless shows electrically determining the location of spinal nerves to be known in the art. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention from the teaching of Feler et al to modify the detection system of Raymond et al '331 by enabling the use for spinal nerves to enable safe operations in the vicinity of the spinal cord.

Claims 15,16,22-26,30,31 and 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raymond et al '153 or 154 in view of Feler et al.

Raymond et al '153 and 154 each disclose applicants' basic inventive concept, a method for determining the location of a nerve by electrically signaling the nerve and detecting the response and determining when the signal is below a threshold signifying

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close proximity to the nerve (see column 3 lines 21-55) and using a visual or audible alarm to signal the proximity to the nerve (column 7 lines 3-23), substantially as claimed with the exception of using the process on a spinal nerve. While this is seen as a matter of design choice since all the nerves in a body function on the same principle, Feler et al nevertheless shows electrically determining the location of spinal nerves to be known in the art. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention from the teaching of Feler et al to modify the detection system of Raymond et al '153 or 154 by enabling the use for spinal nerves to enable safe operations in the vicinity of the spinal cord.

Claims 15,16,22-26,30,32,33,35 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hadzic et al in view of Feler et al.

Hadzic et al discloses applicants' basic inventive concept, a method for determining the location of a nerve by electrically signaling the nerve and detecting the response and determining when the signal is below a threshold signifying close proximity to the nerve (see column 2 lines 1-14) and using a visual means to signal the proximity to the nerve, substantially as claimed with the exception of using the process on a spinal nerve.

While this is seen as a matter of design choice since all the nerves in a body function on the same principle, Feler et al nevertheless shows electrically determining the location of spinal nerves to be known in the art. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention from the teaching of Feler et al to modify the detection system of Hadzic et al by enabling the use for spinal nerves to enable safe operations in the vicinity of the spinal cord.

(11) Response to Argument**A. Raymond '331 in view of Feler '456 render obvious claims 15-16,22-26,30-31 and 33-40.**

Appellant's remarks are all directed to portion a) of claim 15, so the response will be so directed. It is assumed that the detecting and concluding of the latter parts of the claim by the applied references is conceded. Applicant states that none of the references show or teach the identification of nerves as a probe is introduced toward a patient's spine from a lateral direction. Attention is directed to line 42 of column 3 of Feler et al, which discusses "the medial/lateral placement of one or more leads at a given vertebral position of the patient." Feler et al further discuss in line 60 of column 4 "the medial/lateral positioning of stimulation lead(s) 114 with respect to a physiological midline of a patient." This is seen as introducing a lead toward a patient's spine from a generally lateral direction. It is noted that "introduced" as found in the claim requires no insertion into the body of the patient. Placing a probe on the back of a patient is "introducing a lead toward a patient's spine from a lateral direction". Further, treating the spine (and not spinal nerves) as a line, every line which is connectable thereto will have a lateral component with the exception of approaching through the top of the head or the bottom of the pelvis. Using this reasonably broad interpretation of "generally lateral", the references show this feature. Even if one disagrees that this feature is shown directly by the references, the references clearly teach the detection of nerves when approaching the nerves with a probe or tool. None of the references state that such detection will only work for a given approach. This leads an ordinary practitioner

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to assume that the nerve may be approached from any direction, including laterally.

Contrary to appellant's assertion, approaching the spine from the back, front or sides of the patient is still approaching the spine in a "generally lateral direction".

**B. Raymond '153 or '154 in view of Feler '456 render obvious claims
15,16,22-26,30,31 and 33-40.**

Appellant's remarks are all directed to portion a) of claim 15, so the response will be so directed. It is assumed that the detecting and concluding of the latter parts of the claim by the applied references is conceded. Such location of nerves is clearly described in the first two paragraphs under the "Summary of the Invention" heading in column 3 of the Raymond patents. Applicant states that none of the references show or teach the identification of nerves as a probe is introduced toward a patient's spine from a lateral direction. Attention is directed to line 42 of column 3 of Feler et al, which discusses "the medial/lateral placement of one or more leads at a given vertebral position of the patient." Feler et al further discuss in line 60 of column 4 "the medial/lateral positioning of stimulation lead(s) 114 with respect to a physiological midline of a patient." This is seen as introducing a lead toward a patient's spine from a generally lateral direction. It is noted that "introduced" as found in the claim requires no insertion into the body of the patient. Placing a probe on the back of a patient is "introducing a lead toward a patient's spine from a lateral direction". Further, treating the spine (and not spinal nerves) as a line, every line which is connectable thereto will have a lateral component with the exception of approaching through the top of the head or the bottom of the pelvis. Using this reasonably broad interpretation of "generally

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lateral", the references show this feature. It is also noted that figure 1 of Feler et al as well as lines 13-16 of column 6 of the reference teach spinal nerves extending down the arm (see C8). This appears to be the same nerve shown on the front of the Raymond et al patents that has stimulating needle (probe) 22 approaching it from a generally lateral direction. It is further argued that the probe 22 on cover of the Raymond et al patents is being "introduced toward a patient's spine from a generally lateral direction" as currently claimed. Even if one disagrees that this feature is shown directly by the references, the references clearly teach the detection of nerves when approaching the nerves with a probe or tool. None of the references state that such detection will only work for a given approach. This leads an ordinary practitioner to assume that the nerve may be approached from any direction, including laterally. Contrary to appellant's assertion, approaching the spine from the back, front or sides of the patient is still approaching the spine in a "generally lateral direction".

C. Hadzic '151 in view of Feler '456 renders obvious claims 15,16,22-26,30,32-33 and 35.

Appellant's remarks are all directed to portion a) of claim 15, so the response will be so directed. It is assumed that the detecting and concluding of the latter parts of the claim by the applied references is conceded. Nonetheless such a location system is found in lines 33-65 of Hadzic et al. Applicant states that none of the references show or teach the identification of nerves as a probe is introduced toward a patient's spine from a lateral direction. Attention is directed to line 42 of column 3 of Feler et al, which discusses "the medial/lateral placement of one or more leads at a given vertebral

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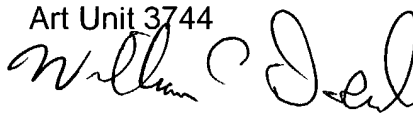
position of the patient.” Feler et al further discuss in line 60 of column 4 “the medial/lateral positioning of stimulation lead(s) 114 with respect to a physiological midline of a patient.” This is seen as introducing a lead toward a patient’s spine from a generally lateral direction. It is noted that “introduced” as found in the claim requires no insertion into the body of the patient. Placing a probe on the back of a patient is “introducing a lead toward a patient’s spine from a lateral direction”. Further, treating the spine (and not spinal nerves) as a line, every line which is connectable thereto will have a lateral component with the exception of approaching through the top of the head or the bottom of the pelvis. Using this reasonably broad interpretation of “generally lateral”, the references show this feature. It is also noted that figure 1 of Feler et al as well as lines 13-16 of column 6 of the reference teach spinal nerves extending down the arm (see C8). This appears to be the same nerve shown on the front of the Hadzic et al patent that has needle 24 approaching it from a generally lateral direction. It is further argued that the needle on cover of the Raymond et al patents is being “introduced toward a patient’s spine from a generally lateral direction” as currently claimed. Even if one disagrees that this feature is shown directly by the references, the references clearly teach the detection of nerves when approaching the nerves with a probe or tool. None of the references state that such detection will only work for a given approach. This leads an ordinary practitioner to assume that the nerve may be approached from any direction, including laterally. Contrary to appellant’s assertion, approaching the spine from the back, front or sides of the patient is still approaching the spine in a “generally lateral direction”.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

William C Doerrler
Primary Examiner
Art Unit 3744



WCD

August 19, 2004

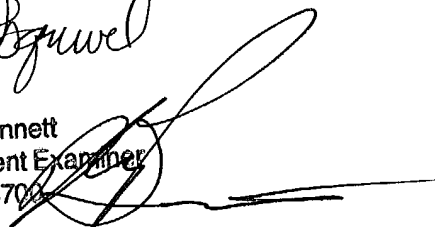
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